

## II

(Non-legislative acts)

## REGULATIONS

## COMMISSION REGULATION (EU) 2021/1317

of 9 August 2021

amending Regulation (EC) No 1881/2006 as regards maximum levels of lead in certain foodstuffs

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food <sup>(1)</sup>, and in particular Article 2(3) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1881/2006 <sup>(2)</sup> sets maximum levels for lead (Pb) in a range of foodstuffs.
- (2) On 18 March 2010, the European Food Safety Authority ('the Authority') adopted an opinion on lead in food <sup>(3)</sup>. The Authority identified that lead can cause developmental neurotoxicity in young children and cardiovascular issues and nephrotoxicity in adults. The risk assessment for lead was based on these potentially critical adverse effects. The Authority concluded that there was no evidence for a threshold for a number of critical endpoints, including developmental neurotoxicity and adult nephrotoxicity. Therefore, it was not appropriate to derive a tolerable weekly intake. The Authority expressed a concern that there was potential that the current levels of dietary exposure to lead might affect neurodevelopment in foetuses, infants and children.
- (3) The Authority's conclusions were confirmed by the conclusions of the report of the Joint FAO/WHO Expert Committee on Food Additives and Contaminants (FAO/WHO) in 2010 <sup>(4)</sup>.
- (4) Taking into account the most recent occurrence data, the Codex Alimentarius Commission at its 41th Session ('CAC41') lowered the Codex maximum level for lead in salt (excluding salt from marshes) from 2 mg/kg to 1 mg/kg.
- (5) Taking into account the most recent occurrence data, the Codex Alimentarius Commission at its 42nd Session ('CAC42') lowered the Codex maximum levels of 0,5 mg/kg for edible offal to 0,2 mg/kg for edible offal from cattle, 0,15 mg/kg for edible offal from pigs and 0,1 mg/kg for edible offal from poultry. It also lowered the maximum levels for 'wine made from grapes' from 0,2 mg/kg to 0,1 mg/kg and set a maximum level for fortified/liqueur 'wines made from grapes' at 0,15 mg/kg. Both maximum levels apply to wine made from grapes harvested after the date the CAC42 adopted the maximum levels.

<sup>(1)</sup> OJ L 37, 13.2.1993, p. 1.

<sup>(2)</sup> Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

<sup>(3)</sup> EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2010. Scientific Opinion on lead in food. *EFSA Journal* 2010;8(4):1570, <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2010.1570>

<sup>(4)</sup> Evaluation of Certain Food Additives and Contaminants. Seventy-third report of the joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series 960.

- (6) In light of these developments and of the most recent occurrence data, the dietary exposure to lead in food should be reduced within the Union by lowering the existing maximum levels or setting additional maximum levels for foodstuffs for which lower levels of lead are reasonably achievable, namely offal, certain foods for infants and young children, salt and wild fungi. For the same reasons, the maximum levels for lead in wines should be reduced and a maximum level for liqueur wine should be established as regards those products produced from future harvests. Finally, for those same reasons, but also to help fight fraudulent practices, such as the addition of lead chromate to turmeric, maximum levels for spices should be established.
- (7) Regulation (EC) No 1881/2006 should therefore be amended accordingly.
- (8) Given that lead is a weak indirect genotoxic carcinogen, and consequently its presence is a higher risk for public health, products not complying with the new maximum levels for lead and placed on the market before the entry into force of this Regulation should only be allowed to remain on the market for a short period of time.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1*

The Annex to Regulation (EC) No 1881/2006 is amended in accordance with the Annex to this Regulation.

*Article 2*

Foodstuffs listed in the Annex that were lawfully placed on the market before the entry into force of this Regulation may remain on the market until 28 February 2022.

*Article 3*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 9 August 2021.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX

In Section 3: Metals of the Annex to Regulation (EC) No 1881/2006, subsection 3.1. (Lead) is replaced by the following:

	Foodstuffs <sup>(1)</sup>	Maximum level (mg/kg wet weight)
3.1	<b>Lead</b>	
3.1.1	Raw milk <sup>(6)</sup> , heat-treated milk and milk for the manufacture of milk-based products	0,020
3.1.2	Infant formulae, follow-on formulae and young child formulae <sup>(57)</sup>	
	marketed as powder <sup>(3) (29)</sup>	0,020
	marketed as liquid <sup>(3) (29)</sup>	0,010
3.1.3	Processed cereal-based foods and baby foods for infants and young children <sup>(3) (29)</sup> other than those listed under point 3.1.5.	0,020
3.1.4	Foods for special medical purposes intended for infants and young children	
	marketed as powder <sup>(3) (29)</sup>	0,020
	marketed as liquid <sup>(3) (29)</sup>	0,010
3.1.5	Drinks for infants and young children labelled and sold as such, other than those mentioned under points 3.1.2 and 3.1.4	
	marketed as liquids or to be reconstituted following instructions of the manufacturer including fruit juices <sup>(4)</sup>	0,020
	to be prepared by infusion or decoction <sup>(29)</sup>	0,50
3.1.6	Meat (excluding offal) of bovine animals, sheep, pig and poultry <sup>(6)</sup>	0,10
3.1.7	Offal <sup>(6)</sup>	
	of bovine animals and sheep	0,20
	of pig	0,15
	of poultry	0,10
3.1.8	Muscle meat of fish <sup>(24) (25)</sup>	0,30
3.1.9	Cephalopods <sup>(52)</sup>	0,30
3.1.10	Crustaceans <sup>(26) (44)</sup>	0,50
3.1.11	Bivalve molluscs <sup>(26)</sup>	1,50
3.1.12	Cereals and pulses	0,20
3.1.13	Root and tuber vegetables (excluding salsifies, fresh ginger and fresh turmeric), bulb vegetables, flowering brassica, head brassica, kohlrabies, legume vegetables and stem vegetables <sup>(27) (53)</sup>	0,10
3.1.14	Leafy brassica, salsify, the following fungi <i>Agaricus bisporus</i> (common mushroom), <i>Pleurotus ostreatus</i> (Oyster mushroom), <i>Lentinula edodes</i> (Shiitake mushroom) and leafy vegetables (excluding fresh herbs) <sup>(27)</sup>	0,30
3.1.15	Wild fungi, fresh turmeric and fresh ginger	0,80

3.1.16	Fruiting vegetables	
	sweetcorn <sup>(27)</sup>	0,10
	other than sweetcorn <sup>(27)</sup>	0,05
3.1.17	Fruit, excluding cranberries, currants, elderberries and strawberry tree fruit <sup>(27)</sup>	0,10
3.1.18	Cranberries, currants, elderberries and strawberry tree fruit <sup>(27)</sup>	0,20
3.1.19	Fats and oils, including milk fat	0,10
3.1.20	Fruit juices, concentrated fruit juices as reconstituted and fruit nectars	
	exclusively from berries and other small fruits <sup>(14)</sup>	0,05
	from fruits other than berries and other small fruits <sup>(14)</sup>	0,03
3.1.21	Wine (including sparkling wine, excluding liqueur wine), cider, perry and fruit wine <sup>(11)</sup>	
	products produced from the 2001 fruit harvest to the 2015 fruit harvest	0,20
	products produced from the 2016 fruit harvest to the 2021 fruit harvest	0,15
	products produced from the 2022 fruit harvest onwards	0,10
3.1.22	Aromatised wine, aromatised wine-based drinks and aromatised wine-product cocktails <sup>(13)</sup>	
	products produced from the 2001 fruit harvest to the 2015 fruit harvest	0,20
	products produced from the 2016 fruit harvest to the 2021 fruit harvest	0,15
	products produced from the 2022 fruit harvest onwards	0,10
3.1.23	Liqueur wine made from grapes <sup>(*)</sup>	
	products produced from the 2022 fruit harvest onwards	0,15
3.1.24	Food supplements <sup>(39)</sup>	3,0
3.1.25	Honey	0,10
3.1.26	Dried spices <sup>(29)</sup>	
	Fruit spices	0,60
	Root and rhizome spices	1,50
	Bark spices	2,0
	Bud spices and flower pistil spices	1,0
	Seed spices	0,90
3.1.27	Salt, except the following unrefined salts: 'fleur de sel' and 'grey salt' which are manually harvested from salt marshes with a clay bottom	1,0
	The following unrefined salts: 'fleur de sel' and 'grey salt' which are manually harvested from salt marshes with a clay bottom	2,0

(\*) As defined in Part II of Annex VII to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).'